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U.S. DISTRICT COURT

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

Alex Hinkley, et al.,
Plaintiffs,

v.

Baker Mills, et al.,
Defendants.

**ORDER DISMISSING COMPLAINT
WITHOUT PREJUDICE**

Case No. 2:21-cv-00221-BSJ

Judge Bruce S. Jenkins

INTRODUCTION

Presently before the Court is Defendants Baker Mills and Kodiak Cakes' "Motion to Dismiss Plaintiffs' First Amended Class Action Complaint" (hereinafter "First Amended Complaint")¹ Plaintiffs Alex Hinkley, Megan Taylor, and Sheila Crawford filed an Opposition.² Defendants filed a Reply.³ The Court heard oral argument on March 25, 2022. Eric Kizirian argued on behalf of Defendants. Hayley Reynolds argued on behalf of Plaintiffs. Having considered the parties' briefing, oral argument, and the applicable law, the Court will DISMISS Plaintiffs' First Amended Complaint on preemption grounds and allow Plaintiffs twenty days to amend their complaint if they so desire.

¹ ECF No. 22.

² ECF No. 32.

³ ECF No. 33.

DISCUSSION

I. Plaintiffs' claims are preempted because they seek to impose limitations on Defendants' packaging greater than those imposed by federal regulation

The Court will dismiss Plaintiffs' First Amended Complaint because Plaintiffs' claims seek to impose limitations on Defendants' packaging that are not identical to those imposed by the Food, Drug and Cosmetics Act ("FDCA") and are, accordingly, preempted. The FDCA contains an express preemption provision which prohibits a State from "directly or indirectly establish[ing] under any authority or continu[ing] in effect as to any food in interstate commerce . . . any requirement for nutrition labeling of food that is not identical to the requirements of" the FDCA. 21 U.S.C. § 343-1. FDCA also provides authority for appropriate regulations, including those related to nutrient-content claims. *See* 21 U.S.C. § 343(q) & (r). "Federal regulations have no less pre-emptive effect than federal statutes." *Fidelity Federal Sav. and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982). Thus, to the extent Plaintiffs' claims seek to impose any requirement for labeling Defendants' food that is "not identical" to the federal statutory and regulatory requirements, the claim is expressly preempted.

a. The applicable regulations permit Defendants to state "14g protein" because such statement does not implicitly characterize the level of protein, nor is it false or misleading

Plaintiffs claim Defendants' label is misleading because it states Defendants' product contains "14g protein" as measured by the so-called nitrogen method. *See, e.g.*, First Amd. Compl. ¶¶ 3–4; Pl.'s Opp. at 6 (ECF No. 32). Plaintiffs argue Defendants should be required to amend their protein-content claim to account for protein quality, using the amino acid score for protein digestibility. *See, e.g.*, First Amd. Compl. ¶ 4–5; 21 C.F.R. § 101.9(c)(7)(i). Contrary to

Plaintiffs' assertions, Defendants' claim on their front label, "14g protein," is permitted by regulation. As a preliminary matter, Plaintiffs point to no regulation that prohibits use of the nitrogen method to measure protein content.⁴ Turning to the applicable regulatory requirements, Defendants' statement is allowed because it does not characterize the level of protein and is not false or misleading. The regulations provide, in pertinent part:

the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if . . . [t]he statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required.

21 C.F.R. § 101.13(i)(3). Defendants' statement here meets these modest requirements. Defendants' packaging states "14g protein." Amd. Compl. ¶ 3. This statement appears to the Court to be functionally identical to the examples of permissible statements listed in the applicable regulation: "(e.g., '100 calories' or '5 grams of fat')."

Plaintiffs did not describe in their brief, nor during oral argument, anything about the statement that is actually misleading. Plaintiffs contend the statement is misleading because the human body cannot digest all of the protein. Yet Defendants' packaging makes no claim or insinuation about protein digestibility. There is no real dispute that Defendants' product contains "14g protein" measured by the so-called nitrogen method. Accordingly, Defendants' statement of protein content by weight is apparently accurate.

⁴ Though the Court finds the material superfluous, the Food and Drug Administration recently released informal guidance indicating nutrient-content claims may be based on the nitrogen method. See U.S. FDA, Indus. Res. Changes Nutrition Facts Label, available at, <https://www.fda.gov/food/food-labeling-nutrition/industry-resources-changes-nutrition-facts-label#LabelClaims> (last visited Apr. 26, 2022).

Also, Plaintiffs spend much of their brief arguing that the statement, “14g protein,” is misleading based on regulations governing the nutrition facts panel. Even assuming the Court should look to those regulations when addressing a nutrition statement found outside the panel, the nutrition-facts-panel regulations expressly permit calculation of protein content using the nitrogen method. *See* 21 C.F.R. § 101.9(c)(7) (“Protein content may be calculated on the basis of the factor 6.25 times the nitrogen content of the food . . .”). Thus, the First Amended Complaint is preempted insofar as it challenges the phrase “14g protein” as a nutrient-content claim where that statement truthfully states protein content as measured by the nitrogen method. Plaintiffs’ claims seek to impose obligations different from the regulations by prohibiting use of the nitrogen method to measure protein and prohibiting a protein claim that is neither false nor misleading.

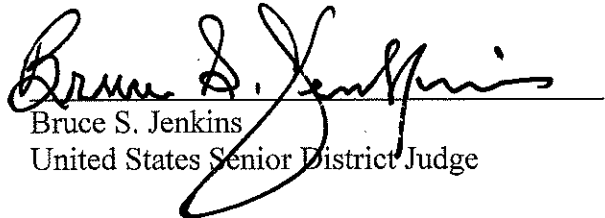
b. The Court will dismiss with leave to amend because the First Amended Complaint is preempted in its current form

Notwithstanding the above, there is a separate question about whether other portions of Plaintiffs’ claims are preempted. Plaintiffs allege additional problems with Defendants’ packaging because, having made a protein-content claim, Defendants were required to provide a “corrected” protein amount, expressed as a “Percent of Daily Value” in the nutrition facts panel. *See* Amd. Compl. ¶ 6; 21 C.F.R. § 101.9(c)(7). This question is presently academic because Plaintiffs’ claims rely so heavily on the suggestion that they were misled by Defendants’ “14g protein” claim based on the method used to determine protein weight. Accordingly, the Court will simply dismiss the First Amended Complaint in its present form and allow Plaintiffs an opportunity to amend if they desire to do so. Plaintiffs may file an amended complaint within twenty days of this order.

ORDER

Based on the foregoing, the Court DISMISSES Plaintiffs' First Amended Complaint (ECF No. 11) because their claims are preempted as stated above. Plaintiffs may file an amended complaint within twenty days of this order.

DATED this 26th day of April 2022.


Bruce S. Jenkins
United States Senior District Judge